

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

TRIPLIXAM **5mg/1.25mg/5mg**
film-coated tablets

TRIPLIXAM **5mg/1.25mg/10mg**
film-coated tablets

TRIPLIXAM **10mg/2.5mg/5mg**
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Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Triplixam is and what it is used for

Triplixam is a combination of three active ingredients: perindopril, indapamide and amlodipine. It is an anti-hypertensive medicine used in the treatment of high blood pressure (hypertension). Patients already taking perindopril/indapamide as fixed dose combination and amlodipine from separate tablets may instead receive one tablet of Triplixam which contains the three active ingredients in the same strength.

Each of the active ingredients reduces blood pressure and they work together to control your blood pressure:

- Perindopril belongs to a class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It works by widening the blood vessels, which makes it easier for your heart to pump blood through them.
- Indapamide is a diuretic (which belongs to a class of medicines called sulfonamide derivatives with an indole ring). Diuretics increase the amount of urine produced by the kidneys. However, Indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.
- Amlodipine is a calcium channel blocker (which belongs to a class of medicines called dihydropyridines). It works by relaxing blood vessels, so blood passes through easily.

2. What you need to know before you take Triplixam

- Do not take Triplixam**
- if you are allergic to perindopril or other ACE-inhibitors, Indapamide or other sulfonamides, amlodipine or other dihydropyridines, or any of the other ingredients of this medicine (listed in Section 6),
 - if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
 - if you have severe liver disease or suffer from a condition called hepatic encephalopathy (disease of the brain caused by liver illness),
 - if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
 - if you take non antiarrhythmic medicines causing life-threatening irregular beat (torsades de pointes)
 - if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body),

- if you suffer from heart failure after a heart attack,
- if you have severe low blood pressure (hypotension),
- if you have low blood potassium,
- if you have severe kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you are receiving dialysis or any other type of blood filtration. Depending on the machine that is used, Triplixam may not be suitable for you,
- if you have moderate kidney problems (for Triplixam doses containing 10mg/2.5mg/5mg and 10mg/2.5mg/10mg),
- if you are more than 3 months pregnant (it is also better to avoid Triplixam in early pregnancy – see pregnancy section),
- if you are breastfeeding,
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing ailsikren,
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see "Warning and Precaution" and "Other medicines and Triplixam").

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Triplixam:

- if you have hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you have heart failure or any other heart problems,
- if you have severe increase in blood pressure (hypertensive crisis),
- if you have liver problems,
- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma,
- if you have atherosclerosis (hardening of the arteries),
- if you need to have a test to check how well your parathyroid gland is working,
- if you suffer from gout,
- if you have diabetes,
- if you are a salt restricted diet or use salt substitutes which contain potassium (a well-balanced potassium blood level is essential),
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with Triplixam should be avoided (see "Taking other medicines"),
- if you are elderly and your dose needs to be increased,
- if you have had photosensitivity reactions,
- if you are black origin you may have higher incidence of angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing) and less effective in lowering blood pressure,
- if you are Haemodialysis patients dialysed with high-flux membranes,
- if you have kidney problems or if you are receiving dialysis,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),

- if you have too much acid in blood, which may cause an increased rate of breathing,
- if you have cerebral circulatory insufficiency (low blood pressure in the brain),
- if you have swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema), which can occur at any time during treatment, stop your treatment immediately and directly contact your doctor;

If you are taking any of the following medicines, the risk of angioedema is increased:

- ailsikren (used to treat diarrhoea),
- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs),
- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure,

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